

Title: Opioid Prescription Usage After Benign Gynecologic Surgery: A Prospective Cohort Study

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Disclosure of Conflicts of Interest

Dr. Lamvu is employed by the U.S. Federal Government. In addition, she served on Ob/Gyn Advisory Boards for Abbvie and Daiichi Sankyo and received research funding from Pfizer Inc. The other authors have no conflicts of interest.

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Presentations

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Precis: In this prospective study, gynecologic surgeons over-prescribed opioids almost three times more than was used by patients after minor and major surgical procedures.

Keywords: Opioids, post-operative pain, post-operative opioids, gynecology, gynecologic surgery.

Abstract

Study Objective: To compare the amount of opioids (tablets and morphine milligram equivalents-MME) prescribed by physicians and used by patients, after benign gynecologic surgery.

Design: Prospective Cohort Study

Setting: Tertiary Center- Main Hospital Operating Room and Outpatient Surgery Center

Patients: Women undergoing benign gynecologic surgery

Interventions: Major and minor gynecologic surgeries

Measurements: The surgery groups were: 1) minor laparoscopy (Minor), 2) major minimally invasive (Major) and 3) laparotomy (Laparotomy). Demographic, medical and surgical data was abstracted from electronic medical records. On post-operative day (POD) 7, women completed a telephone survey describing pain levels, prescription use and satisfaction with pain control. Patients who continued to use opioids for pain relief were surveyed on POD 14. If use continued, patients were surveyed again on POD 28. The primary outcome was amount of opioid prescribed compared to used.

Main Results: Of 193 screened participants, 172 were enrolled (89%) and data was analyzed for 154 (90%): 59 (38%) Major, 71 (56%) Minor, and 24 (16%) Laparotomy. The median number of tablets and MME prescribed was lowest for the Minor group (Minor 24 tablets, Major 30 tablets and Laparotomy 30 tablets, $p < 0.01$; Minor 150 MME, Major 225 MME, Laparotomy 225 MME, $p = 0.01$). We found no difference in the number of tablets (Minor 8, Major 8, Laparotomy 9, $p = 0.77$) or MME used (Minor 45 MME, Major 45 MME, Laparotomy 55 MME, $p = 0.81$) between the groups. On POD 7 there was no difference in median Numerical Rating Scale (NRS) pain scores (Minor 3, Major 2, Laparotomy 2, $p = 0.07$) or satisfaction with analgesia on post-operative day 7 ($p = 0.44$), day 14 ($p = 0.87$), and day 28 ($p = 0.18$). Patients with prior chronic pain used more total amount of opioids (68 MME vs. 30 MME, $p < 0.01$) and were more likely to require opioid refill (OR 10.4; 95% CI 1.3-83.6) compared to those without a similar history.

Conclusion: In this cohort, gynecologic surgeons prescribed nearly three times more opioid tablets and MME than was used by patients despite patients reporting similar levels of pain after minor and major surgeries.

Introduction

Opioid abuse is considered a nationwide epidemic that is partially attributed to healthcare provider prescription practices. A survey of Americans who received opioid prescriptions for pain management revealed that more than half had left-over opioid prescriptions and most of those individuals (61.3%) planned on saving the opioids for future use.¹ Another national survey showed that of people who use prescription opioids recreationally, 56.5% received the opioid for free from a friend or relative, and 81% of those friends or relatives received the medication from a physician.² This data suggests that to curtail the opioid abuse epidemic, it will be imperative for physicians to avoid overprescribing opioids.

In gynecology, as in other surgical fields, one of the most common reasons for prescribing an opioid is for pain control after surgery. Studies by As Sanie et al and Wong et al described excessive opioid prescriptions after hysterectomy at their institutions.^{3,4} Evidence indicates a 5-6% risk of persistent opioid use in opioid naïve patients following hysterectomy.⁵ Despite these findings, there are no current guidelines for the amount of opioids that should be prescribed for pain management after gynecologic surgery.

Our study aims are 1) to expand the current body of research and 2) to assess the amount of opioid medication typically prescribed after a variety of minimally invasive and open gynecologic procedures and 3) to assess the amount of opioid medication that patients use after they are discharged home. Along with prior research, our study may help with the development of future guidelines detailing the amount of opioid that should be prescribed after gynecologic surgery based on patients' post-operative opioid usage.

Material and Methods

Institutional Review Board (IRB) approval was obtained through Florida Hospital, IRB #948553. Participants were enrolled from November 1, 2016 to December 1, 2017 and recruited in the pre-operative holding areas of the hospital and ambulatory surgical center of Florida

Hospital, Orlando, FL. Patients were included if they were undergoing benign gynecologic surgery via either laparoscopy, major minimally invasive techniques or laparotomy, 18 years of age or older, able to provide informed consent, able to provide two contact phone numbers, and able to read and speak English. Exclusion criteria included 1) intolerance/allergy to multiple opioid pain medications, 2) undergoing only hysteroscopy, dilation and curettage, or minor vaginal procedures such as cold knife cone, anterior/posterior repair, or sling placement, 3) a diagnosis of gynecologic malignancy, 4) pregnancy, 5) change of address more than 3 times in the past 6 months and 6) lack of a reliable method of contact.

A case report form was used to abstract demographic, medical and surgical data from subjects' electronic medical record. After informed written consent was obtained, the patient's chart was reviewed for demographic information, medical/surgical history, procedure indication, procedure type, final pathology diagnosis, prescription medications and amounts prescribed, and day of discharge. Those who had the following diagnoses listed in their past medical history on the pre-operative visit chart were classified as having a prior chronic pain syndrome: 1) Chronic Back Pain, 2) Chronic Headache, 3) Migraine, 4) Chronic Fatigue Syndrome, 5) Fibromyalgia, 6) Chronic Pelvic Pain, 7) Rheumatoid Arthritis, 8) Painful Bladder Syndrome, and 9) Irritable Bowel Syndrome. Patients were stratified into 3 groups: 1) minor laparoscopy (Minor), 2) major minimally invasive (Major), and 3) laparotomy (Laparotomy). Minor laparoscopic surgeries included diagnostic laparoscopy, laparoscopic ovarian cystectomy, laparoscopic salpingectomy or salpingo-oophorectomy, laparoscopic excision of stage 1-2 endometriosis and laparoscopic bilateral tubal ligation. Major minimally invasive surgeries included laparoscopic/robotic hysterectomy, sacrocolpopexy, myomectomy, excision of stage 3-4 endometriosis and vaginal hysterectomy. Laparotomy surgeries included any benign gynecologic surgery that required laparotomy including total abdominal hysterectomy and abdominal myomectomy.

Subjects were contacted by telephone on post-operative day (POD) 7 using a telephone script. They were asked about pain levels, satisfaction with pain management, prescription medication usage, refill requests, number of opioid tablets left over and medication disposal. If the participant stopped using opioid medication by POD 7 then she was no longer contacted. If she was still using opioid analgesics then she was contacted with a similar standardized survey on POD 14 and then again on POD 28 if she was still using opioid medication.

The primary outcome measures were number of opioid tablets and amount of MME used after discharge from surgery as compared to the number of opioid tablets and amount of MME prescribed. There was no data for post-operative opioid usage in obstetrics and gynecologic field when we began our research, therefore we calculated our sample size based on data from a previous study in urology.⁶ Patients used on average 22-24 tablets after urologic surgeries. A sample size of 60 in each group (minimally invasive minor, minimally invasive major and open) was determined to be adequate to detect a difference of at least 5 pills between the three surgery groups with an alpha error of 0.05 and power of 80% and assuming a 15% loss to follow-up. After data was available in the field of gynecology, we also completed a post-hoc power analysis to ensure we had obtained adequate sample sizes. Based on a study focused on urogynecologic procedures⁷, patients used a mean of 14 tablets of opioids with standard deviation of 8.3. A sample size of 44 in each group (minor laparoscopy, major minimally invasive and laparotomy) would be adequate to detect a difference of at least 5 pills with an alpha error of 0.05 and power of 80%.

All study data was stored in Epi Info V7.0, Atlanta, GA: CDC. To compare types of opioids, prescriptions were converted to MME. Statistical analysis was completed using IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp.

Data values were summarized as frequency and percent for categorical variables. For continuous variables, non-normally distributed variables were reported as median and interquartile range while normally distributed variables were reported as mean and standard

deviation. Continuous variables were examined for normality. Depending on the distribution of the data, we used analysis of variance (ANOVA), Kruskal-Wallis or Mann-Whitney tests to describe differences between the study groups. For categorical variables, we used the Chi-square test or Fisher's Exact if the numbers in each cell were less than 5.

Results

Of 193 screened participants, 172 enrolled in the study (Figure 1). Nine patients were lost to follow-up or did not respond to surveys and an additional 9 patients were withdrawn from the study; 154 had complete data for analysis. Women were withdrawn for the following reasons: 1) patient no longer wanted to be in the study, 2) patient's final surgical pathology was found to be malignant (an exclusion criteria), 3) patient's final surgery was more complex than allowed by inclusion criteria and included procedures such as excision of bowel or appendectomy. Target sample sizes were achieved for both minor laparoscopy and major minimally invasive groups. The study was closed prior to achieving sample size for the laparotomy group due to the low volume of benign laparotomy surgeries performed at our institution. The decision was made because even in the laparotomy group, patients were using less opioids than prescribed (primary outcome measure).

Clinical characteristics of the study cohort are summarized in Table 1; patients in all three groups had similar characteristics except for age: Minor 37 years (21-72), Major 46 years (27-75) and Laparotomy 46 years (36-67), $p < 0.01$. The prevalence of obesity, anxiety, depression and chronic pain was similar in all three groups.

Surgeons' prescribing practices varied widely and the types of opioids prescribed included: acetaminophen-oxycodone 5/325 mg ($n = 84$, 55%), acetaminophen-hydrocodone 5/325 mg ($n = 5$, 33%), acetaminophen-hydrocodone 7.5/325 mg ($n = 2$, 1%), hydromorphone 2 mg ($n = 8$, 5%), tramadol 50 mg ($n = 1$, 1%), and others ($n = 7$, 5%). Figure 2 and Table 2 describe the tablets of opioids and the MME amount of opioid prescribed and used. For the

entire cohort, the median number of opioid tablets prescribed was 30 (24-30), and the median MME was 200 (150-225). The median number of tablets prescribed for the minor laparoscopy group was 24 (20-30), for major minimally invasive group was 30 (30-40), and for laparotomy was 30 (30-35), $p < 0.01$. After converting the tablets to MME, the mean MME prescribed was also found to be statistically different, $p = 0.01$. Patients in the minor laparoscopy group were prescribed a significantly lower number of opioid tablets and MME amount when compared to patients in the major minimally invasive and laparotomy group.

There was no statistical difference in the number of opioid tablets or MME used post-operatively in the 3 surgery groups (Table 2). The median number of opioid tablets used by patients post-operatively in the minor laparoscopy group was 8 (2-20), in the major minimally invasive group was 8 (0-20), and in the laparotomy group was 9 (0-21), $p = 0.77$. Mean MME used in the minor laparoscopy group was 45 (4-120), in the major minimally invasive group was 45 (0-140), and in the laparotomy group was 55 (8-143), $p = 0.81$. There were 31 patients (20%) who did not use any opioids post-operatively - Minor 11 (20%), Major 16 (24%), and Laparotomy 4 (17%). Only 11 patients (8%) received opioid refills.

Patients who reported a history of chronic pain syndrome used two times more opioids post-operatively compared to patients without a chronic pain syndrome diagnosis (68 MME, 0-113 MME vs. 30 MME, 41-165 MME, $p < 0.01$, Figure 3). Patients who underwent surgery specifically for chronic pelvic pain used 3 times more opioids post-operatively compared to those whose surgeries were for non-pain indications (100 MME, 15-159 MME vs. 30 MME, 0-99 MME, $p < 0.01$). The patients who reported a history of chronic pain syndrome were also prescribed more total opioids (initial prescription and subsequent refills) compared to the patients without a chronic pain syndrome history (223 MME, 150-225 MME vs. 194 MME, 150-225 MME, $p < 0.01$). However, there was no difference in the amount of MME initially prescribed for patients with and without history of chronic pain syndrome (197 MME, 150-225 MME vs. 191 MME, 150-225 MME, $p=0.62$). Of the 11 patients who received refills, 10 patients

(91%) had a history of chronic pain syndrome. Patients who reported a history of chronic pain syndrome were 10 times more likely to need a refill than patients who did not report a history of chronic pain syndrome (OR 10.4; 95% CI 1.3-83.6). There was no difference in the total amount of morphine taken for pain for patients reporting anxiety ($p = 0.36$) or depression ($p = 0.25$) compared to patients without these disorders.

After surgery, opioids were used for a median of 5 days for Minor (2-9), 5 days for Major (1-11) and 6 days for Laparotomy (3-13) groups, $p=0.14$. By POD 7, 66% of patients stopped using opioids in the Minor group, 68% in the Major group, and 70% in the Laparotomy group. By POD 14, 90% of patients in the study stopped using opioids.

Distribution of pain satisfaction and pain scores are shown in Table 3. On POD 7, 93% of patients were very satisfied or somewhat satisfied, with their pain management. Among the patients who were still taking opioid medications on POD 14, 83% of patients were very satisfied and among those still taking opioid medications on POD 28, 79% of patients were very satisfied. There was no difference in satisfaction with pain management between the groups on POD #7. Majority of patients reported no pain or mild pain at POD 7 (72%), POD 14 (67%) and POD 28 (83%). There was no difference in mean pain score for patients in the 3 different surgery groups at POD 7, 14 or 28. Only 7 patients (5%) reported they were instructed in proper disposal of leftover opioid medications.

Discussion

In this study population, women were prescribed more than 3 times the number of opioid tablets that they actually used; median 30 tablets prescribed versus 8 tablets actually used. When tablet numbers are converted to MME, patients in the minor laparoscopy group were prescribed 2.5 times more MME than amount used, and patients in the major minimally invasive and laparotomy groups were prescribed 4 times more. The study shows that gynecologic surgeons prescribe more opioids than needed, which is consistent with recent publications regarding prescribing patterns following hysterectomies.^{3,4,7} Our study provides additional data

on prescription patterns by focusing on a wider variety of gynecologic surgeries, other than hysterectomy, and including major and minor laparoscopic procedures.

We noted that patients in our study report similar post-operative pain levels and opioid medication use regardless of whether they underwent minor laparoscopic surgery, major minimally invasive surgery or laparotomy. Similar findings were found by Griffith et al when comparing prescription opioid usage between patients who underwent minimally invasive hysterectomies versus abdominal hysterectomies.⁸ In our cohort, the mean hospital stay for patients who underwent major minimally invasive procedures was 1 day versus 3 days for the laparotomy group. Therefore, at the time of discharge, it would be expected that pain levels for laparotomy patients would be similar to those experienced by patients who underwent minimally invasive procedures and were discharged two days prior. Irrespective of the similarities in pain levels, patients were over-prescribed opioids for both minor and major procedures.

In this cohort, having a chronic pain syndrome was associated with a two-fold increase in the amount of opioid used. Furthermore, patients who had chronic pelvic pain as the primary indication for surgery, had a three-fold increase in opioid usage. However, it is important to note that even in the chronic pain cohort, opioids tended to be over-prescribed. For example, patients with chronic pain averaged 100 MME used vs. 223 MME prescribed. Our study is consistent with other publications showing that a history of pain syndromes was associated with increased opioid usage among patients who had undergone hysterectomy.^{3,4} Prior research supports the hypothesis that patients with a history of multiple chronic pain disorders might be less successful at achieving adequate pain relief when compared to patients without a history of chronic pain disorders.^{9,10} These findings emphasize the need for pre-operative screening to identify chronic pain co-morbidities and the need for more research on how to adequately adjust post-operative pain management in this patient population.

Less than 5% of patients reported being instructed on how to dispose of left-over opioid medications. Previous studies show that the majority of first-time opioid abusers receive the

medication from a friend or relative with left-over medication.² Moreover, our research suggests that in addition to reducing over-prescribing, better patient education on proper disposal of opioids is another factor important in decreasing access to and abuse of opioids. A survey of obstetrician-gynecologists completed by Madsen et al showed that 44% of providers did not know proper disposal guidelines for prescription opioids.¹¹ To aid healthcare providers, the FDA and DEA provide guidelines regarding the disposal of opioid medications which can easily be referenced or given to patients as part of post-operative education.¹²

Strengths of our study include collecting data from a wide variety of gynecologic procedures, diverse patient population and low loss to follow-up. Although our study is limited to a relatively small sample from a single tertiary care center, we are reassured that our findings are consistent with published studies,^{3,4,7,8,13} confirming that patients are over-prescribed post-operative opioids across specialties and study populations.

While the planned sample sizes for the minor laparoscopy and major minimally invasive groups were reached, we were unable to reach the target sample size for benign laparotomies. Therefore, the findings seen in the laparotomy group were not adequately powered to make definitive negative conclusions and future studies are needed to determine the significance of our findings. Data regarding chronic opioid use before surgery was not collected, and thus we could not determine if increased opioid consumption prior to surgery correlated to increased use after surgery in patients with chronic pain. At the time of this study, ERAS protocol was not universally in place at our institution's surgery centers, therefore patients might have received varied amounts and types of analgesia in the operating room and PACU. Also, accuracy of electronic medical record diagnoses for chronic disorders may sometimes be inaccurate and for this study, diagnoses were found in provider clinical notes as well as operative and pathology reports. In addition, while patients were specifically asked to count the number of opioid tablets they had left over from their prescription, we relied on patient report to determine the number of excess tablets.

Overall, this study's findings support the growing body of data confirming that physicians, including gynecologists, are over-prescribing opioid medications after surgery. In this cohort, patients with known chronic pain syndromes may have increased opioid needs or may need better adjuvant medications to achieve adequate pain control. A predictive calculator to tailor opioid prescriptions based on patient pre-operative characteristics has been proposed by Wong et al, but it is specific to laparoscopic hysterectomy.⁴ Further research is needed to develop a similar calculator for a wider range of gynecologic procedures. Further awareness and education is needed for both providers and patients, so that opioids are appropriately prescribed to meet patients' analgesic requirements while left-over medications are safely disposed.

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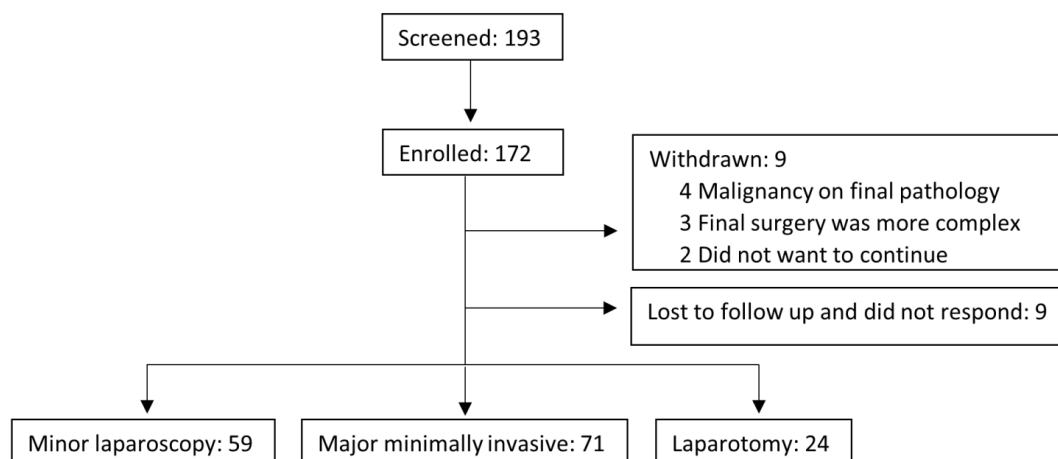
Figure Legends

Figure 1: Patient flow diagram

Depiction of subject recruitment and inclusion/exclusion.

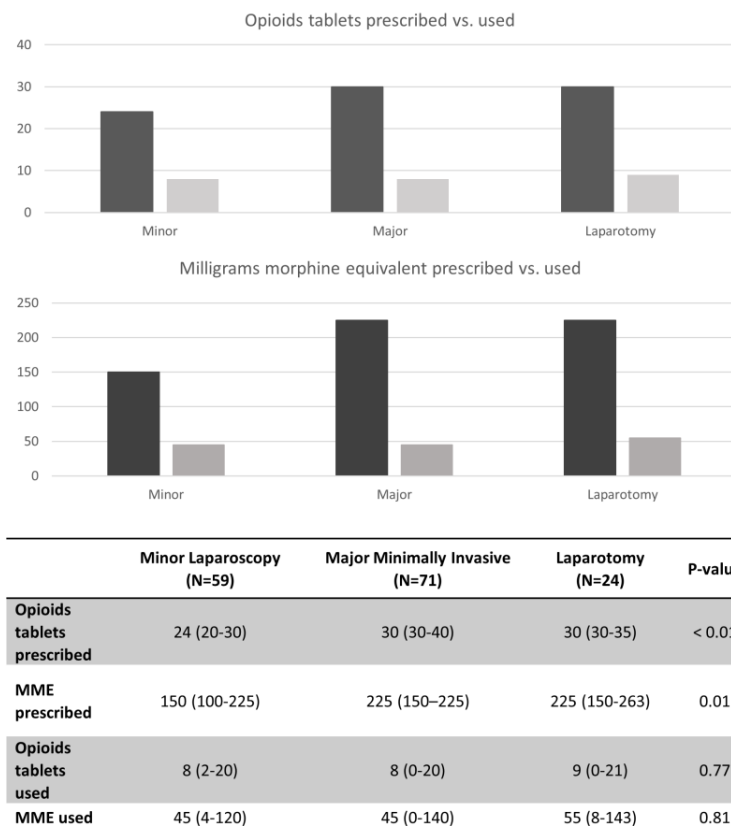


Figure 2: Patterns of opioid prescription and usage

Comparison of amount of opioids prescribed (dark gray) versus amount actually used (light gray). A difference of greater than 5 tablets was considered clinically significant. Data presented as median (interquartile range). P-values calculated for comparisons between the minor laparoscopy group, major minimally invasive, and laparotomy groups.

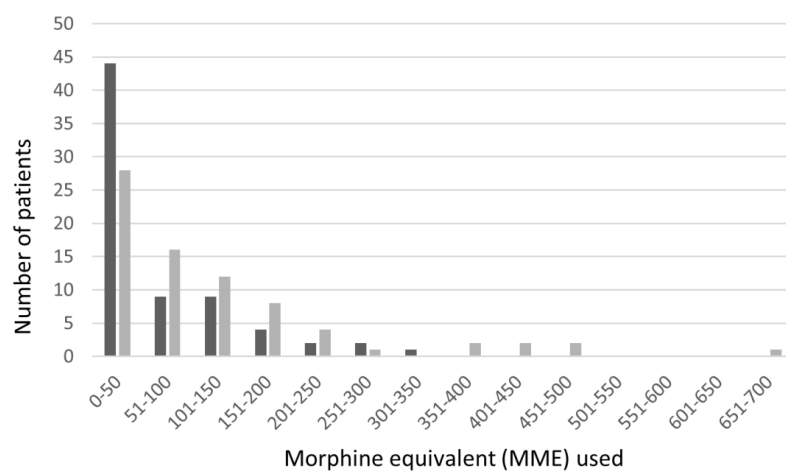


Figure 3: Opioid usage stratified by chronic pain syndrome history

Amount of opioids used by subjects without a chronic pain syndrome (dark gray) compared to those with a chronic pain syndrome (light gray).

Table 1. Baseline demographics of study population

	All (N = 154)	Minor (N = 59)	Major (N = 71)	Laparotomy (N = 24)	p-value ^d
Age ^a	42 (12)	37 (11)	46 (13)	46 (6)	<0.01
Race ^b					0.65
White	97 (63)	41 (70)	47 (67)	9 (38)	
Black	41 (26)	11 (19)	17 (24)	13 (54)	
Asian	0	0	0	0	
American-Indian/Alaskan	2 (1)	1 (2)	0	1 (4)	
Hispanic/Latino	0	0	0	0	
Other	13 (9)	6 (10)	6 (9)	1 (4)	
BMI ^a	29 (7)	29 (8)	29 (6)	28 (8)	0.36
Obesity ^b	56 (36)	21 (36)	24 (34)	11 (46)	0.56
Insurance type ^b					0.60
No insurance	19 (13)	9 (16)	7 (10)	3 (13)	
Private	107 (71)	40 (71)	49 (69)	18 (78)	
Medicare	18 (12)	3 (5)	13 (18)	2 (9)	
Medicaid	6 (4)	4 (7)	2 (3)	0	
Chronic pain syndrome ^b	79 (51)	26 (45)	43 (61)	10 (42)	0.12
Anxiety ^b	18 (12)	3 (5)	12 (17)	3 (13)	0.09
Depression ^b	15 (10)	4 (7)	7 (10)	4 (2)	0.37
LOS ^c	0 (0-1)	0 (0-0)	1 (0-1)	3 (2-3)	0

^a Data presented as mean (standard deviation)^b Data presented as n (%)^c LOS = length of hospital stays in days; Data reported as median (interquartile range)^d p-values calculated for comparisons between the minor laparoscopy group, major minimally invasive, and laparotomy groups

Table 2: Prescription opioids prescribed and used post-operatively

	Minor (N=59)	Major (N=71)	Laparotomy (N=24)	P-value
Opioids tablets prescribed	24 (20-30)	30 (30-40)	30 (30-35)	< 0.01
MME prescribed	150 (100-225)	225 (150–225)	225 (150-263)	0.01
Opioids tablets used	8 (2-20)	8 (0-20)	9 (0-21)	0.77
MME used	45 (4-120)	45 (0-140)	55 (8-143)	0.81

Data reported as median (interquartile range).

Table 3. Post-operative pain levels and satisfaction with pain control

	Minor	Major	Laparotomy	P-value
Pain NRS Score ^a				
POD 7	3, (1-4, n=56)	2, (1-4, n=70)	2, (1-4, n= 21)	0.27
POD 14 ^b	2, (0-4, n=21)	3, (1-4, n=25)	3, (1-5, n=10)	0.46
POD 21 ^b	2, (1-4, n=7)	1, (0-3, n=12)	0, (0-1, n=5)	0.22
Satisfaction with pain control				
POD 7 ^c				0.44
Very satisfied	43 (77)	57 (81)	14 (71)	
Somewhat satisfied	7 (13)	11 (16)	4 (19)	
Neither satisfied nor dissatisfied	4 (7)	0	0	
Somewhat dissatisfied	1 (2)	0	1 (5)	
Very dissatisfied	1 (2)	0	1 (5)	
POD 14 ^{b,c}				0.87
Very satisfied	18 (86)	21 (84)	8 (80)	
Somewhat satisfied	1 (5)	4 (16)	2 (20)	
Neither satisfied nor dissatisfied	2 (10)	0	0	
Somewhat dissatisfied	0	0	0	
Very dissatisfied	0	0	0	
POD 28 ^{b,c}				0.18
Very satisfied	6 (86)	10 (83)	3 (60)	
Somewhat satisfied	1 (14)	2 (17)	1 (20)	
Neither satisfied nor dissatisfied	0	0	0	
Somewhat dissatisfied	0	0	1 (20)	
Very dissatisfied	0	0	0	

^a Data presented as median, (interquartile range, sample size)

^b Recorded only if participant was still taking pain medication

^c Data presented as n (%)